REMARKS

Claims 1, 3-5, 9-15, 21, 23-25 and 32 are pending in the present application. Claims 2, 6-8, 16-20, 22, 26-31 and 33-45 have been previously canceled without prejudice or disclaimer. Claims 1, 5, 9-15, 21, 23 and 32 have been amended.

Applicants, by canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

Claim 1 has been amended to recite a "method for treating an inflammatory disease, an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer, prostate cancer, pancreatic cancer, and lung cancer in a patient, comprising: simultaneous or step-wise administering of curcumin, curcumin analogue or derivative thereof and at least one NSAID to the patient, the curcumin , curcumin analogue or derivative thereof being administered in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the NSAID alone, wherein the NSAID is selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug

thereof." Support for this amendment can be found throughout the specification and claims as originally filed.

Claim 5 has been amended to recite the "method according to claim 1, wherein said curcumin, curcumin analogue or derivative thereof is a curcumin analogue or derivative selected from the group consisting of demethoxycurcumin and bisdemethoxycurcumin." Support for this amendment can be found throughout the specification and claims as originally filed.

Claims 9-11 have been amended to depend from claim 1. Support for these amendments can be found throughout the specification and claims as originally filed.

Claim 12 has been amended to recite a "method for inhibiting cancer cell growth, comprising: contacting cancer cells with an effective amount of curcumin, a curcumin analogue or derivative thereof and an effective amount of at least one NSAID selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof, wherein the curcumin, curcumin analogue or derivative thereof is present in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the at least one NSAID alone, and wherein the curcumin, curcumin analogue

or derivative thereof and the at least one NSAID are administered simultaneously, sequentially or separately." Support for this amendment can be found throughout the specification and claims as originally filed.

Claims 13-15, 20 and 23 have been amended to be placed in proper US claim format. In particular, claims 13-15 have been amended to recite "...curcumin, curcumin analogue or derivative thereof..." rather than "curcumin" alone. Claim 20 has been amended to depend from claim 1. Claim 23 has been amended to recite "inflammatory disease or inflammatory_disorder" rather than inflammatory disease or disorder." Support for these amendments can be found throughout the specification and claims as originally filed.

Claim 32 has been amended to recite a "combination of two pharmaceutical compositions, comprising: a first composition comprising an effective amount of at least one NSAID drug selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof; and a second composition comprising an effective amount of curcumin, a curcumin analogue or derivative thereof, the combination being intended for administering to a subject for treatment of an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer,

prostate cancer, pancreatic cancer, and lung cancer, wherein the second composition is administered after administering the first composition." Support for this amendment can be found throughout the specification and claims as originally filed.

No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 8 of the Official Action, claim 13 has been objected to.

The Examiner objects to claim 13 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants submit that the objection to claim 13 has been obviated in view of the amendment to claim 12. In this regard, Applicants note that claim 12 no longer recites "a formulation..." and provides for separate and concomitant administration of the curcumin and NSAID. In contrast, claim 13 is directed to administering a formulation comprising both the curcumin, analogue or derivative thereof and the NSAID. Accordingly, reconsideration and withdrawal of this objection is respectfully rejected.

II. At page 8 of the Official Action, claims 1, 3-5, 9-15, 20, 23-25 and 32 have been rejected under 35 USC § 112, first paragraph.

The Examiner asserts that "while being enabling for treating an inflammatory disease or disorder, treating colorectal, prostate, pancreatic and lung cancers, inhibiting cancer cell growth such as the cumin colon carcinoma cell line Caco-2 and HT-29, depicted in the figures and tables, , it does not reasonably provide enablement for treating any "disorder" or any other cancer." *See* the Official Action at page 8.

In view of the following, the rejection of claims 1, 3-5, 9-15, 23-25 and 32 is respectfully traversed. In addition, Applicants note that the cancellation of claim 20 has rendered the rejection of the same moot.

Applicants note that claim 1 has been amended to recite a "method for treating an inflammatory disease, an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer, prostate cancer, pancreatic cancer, and lung cancer in a patient...." In addition, claim 12 is directed to a method of inhibiting cancer cell growth. Further, claim 32 has been amended to recite that "the combination being intended for administering to a subject for treatment of an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer, prostate cancer, pancreatic cancer, and lung cancer." The remaining rejected claims each depend, either directly or indirectly from claims 1, 12 or 32.

As indicated by the Examiner in the cited passage appearing on page 8 of the Official Action, the specification is enabling "for treating an inflammatory disease or disorder, treating colorectal, prostate, pancreatic and lung cancers, inhibiting cancer cell growth such as the cumin colon carcinoma cell line Caco-2 and HT-29, depicted in the figures and tables." Applicants submit that, as amended, the specification is enabling for all of the presently pending claims.

Therefore, Applicant submits that the instant application enables the skilled artisan to make and use the full scope of the subject matter as claimed, within the meaning of 35 USC § 112, first paragraph. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

III. At pages 12 of the Official Action, claims 5, 9-11, 14 and 15 have been rejected under 35 USC § 112, second paragraph.

The Examiner asserts that the claims are indefinite for the reasons set forth in the Official Action.

Applicants respectfully submit that the amendments to claims, submitted herewith, obviate the rejections to claims 5, 9-11, 14 and 15. In particular, the alleged antecedent basis deficiencies have now been cured.

Accordingly, Applicants respectfully submit that all of the pending claims are clear and definite within the meaning of 35 USC § 112. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

IV. At page 13 of the Official Action, claim 12 has been rejected under 35 USC § 102(b) as being anticipated by Thun et al. (of record).

The Examiner asserts that Thun et al. describe every element of claim 12.

In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 12 is directed to a method ***for inhibiting cancer cell growth***, comprising: ***contacting cancer cells*** with an effective amount of curcumin, a curcumin analogue or

derivative thereof and an effective amount of at least one NSAID selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof, wherein the curcumin, curcumin analogue or derivative thereof is present in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the at least one NSAID alone, and wherein the curcumin, curcumin analogue or derivative thereof and the at least one NSAID are administered simultaneously, sequentially or separately. (Emphasis added).

Applicants note that claim 12 is directed to inhibiting the growth of cancer cells where cancer cells already exist. In this regard, Applicants note that the term "inhibiting" is defined in the present specification at page 17, lines 6-13 as achieving at least one of the following: decrease in the number of cells as compared to the control, decrease in tumor size, decrease in rate of tumor growth, inhibition of proliferation, stasis of tumor size, decrease in the number of metastasis, decrease in the number of additional metastasis, decrease in the invasiveness of the cancer, decrease in the rate of progression of the tumor from one stage to the next as well as decrease in the angiogenesis induced by the cancer. In addition, claim 12 requires contacting a cancer cell. Thus, claim 12 is not

directed to preventing cancer where no cancer already exists.

In complete contrast, Thun et al. is directed to preventing colon cancer in individuals with average or above average risk of colon cancer. The patients are, thus, cancer free. *See* Thun et al. at table 2, page 260. In addition, Applicants respectfully direct the Examiner's attention to a more detailed description of the study mentioned in Table 2 of Thun et al., which has the ID number of NCI-V98-1425(425') as indicated in column 1 (from the left) of Table 2 (line 16). The 425' study may be viewed at: http://clinicaltrials.gov/ct2/show/NCT00003365. In addition a copy of the same is submitted herewith for the Examiner's convenience.

Study 425' describes a clinical trial arranged to study the effectiveness of sulindac and curcumin (among other agents) for preventing colon cancer. The study was conducted on normal volunteers at average or above average risk of colon cancer. Since the clinical trial in the 425' study was conducted on individuals that, at the time the trials were conducted, did not suffer from cancer, inhibition of cancer could not have been demonstrated in the study, within the meaning of claim 12. As set forth on pages 2-3 of the 425' study, the eligibility criteria for participants in the clinical trial includes having an average risk or above average risk of developing colon cancer, but does not include individuals suffering from colon cancer. Therefore, the 425' study does not anticipate 'a method for inhibiting cancer' as claimed in claim 12.

In view of the foregoing, it is submitted that claim 12 is novel over Thun et al. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

V. At page 12 of the Official Action, claims 1, 3, 4, 10, 12-15, 20, 21, 25 and 32 have been rejected under 35 USC § 103(a) as being unpatentable over Thun et al. and Kawamori et al. (Cancer Research Vol. 59, 597-601, February 1, 1999).

The Examiner asserts that claims 1, 3, 4, 10, 12-15, 20, 21, 25 and 32 are obvious for the reasons set for the in the Official Action.

In view of the following, the rejection of claims 1, 3, 4, 10, 12-15, 21, 25 and 32 is respectfully traversed. In addition, Applicants note that the cancellation of claim 20 has rendered the rejection of the same moot.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the

invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson,* 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants submit that a *prima facie* case of obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest every element of the pending claims.

Independent claim 1 is directed to a method for treating an inflammatory disease, an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer, prostate cancer, pancreatic cancer, and lung cancer in a patient, comprising: simultaneous or step-wise administering of curcumin, curcumin analogue or derivative thereof and at least one NSAID to the patient, the curcumin , curcumin analogue or derivative thereof being administered in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the NSAID alone, wherein the NSAID is selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof. The remaining rejected claims depend, either directly or indirectly from claims 1 and 12.

Independent claim 12 is directed to a method for inhibiting cancer cell growth, comprising: contacting cancer cells with an effective amount of curcumin, a curcumin analogue or derivative thereof and an effective amount of at least one NSAID selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin, fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof, wherein the curcumin, curcumin analogue or derivative thereof is present in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the at least one NSAID alone, and wherein the curcumin, curcumin analogue or derivative thereof and the at least one NSAID are administered simultaneously, sequentially or separately. The remaining rejected claims depend, either directly or indirectly from claims 1 and 12.

Claim 32 is directed to a combination of two pharmaceutical compositions, comprising: a first composition comprising an effective amount of at least one NSAID drug selected from the group consisting of ketorolac, nabumetone, salsalate, diclofenac, indomethacin, nabumetone, phenylbutazone, oxyphenbutazone, dipyrone, ramifenazone, tenoxicam, valdecoxib, parecoxib, etoricoxib, celecoxib, sulindac, sulindac sulfide, exisulind, ibuprofen, naproxen, naproxen sodium, rofecoxib, nimesulide, aspirin, tolmetin,

fenoprofen, flurbiprofen, loxoprofen, vedaprofen, meclofenamic acid, meclofenamate sodium, tolfenamic acid, acetaminophen, flunixin, piroxicam, oxaprozin, meloxicam, ketoprofen, etodolac and diflunisal, or a salt or prodrug thereof; and a second composition comprising an effective amount of curcumin, a curcumin analogue or derivative thereof, the combination being intended for administering to a subject for treatment of an inflammatory disorder or a cancer selected from the group consisting of colorectal cancer, prostate cancer, pancreatic cancer, and lung cancer, wherein the second composition is administered after administering the first composition.

Applicants submit that the presently claimed methods and composition are each, in part, directed to using curcumin, analogues and derivatives thereof, to reduce the NSAID concentration needed for treatment, while maintaining the same therapeutic effect as compared to administering the NSAID alone.

With regard to the combination of an NSAID and curcumin, Applicants submit that Thun et al. is directed to the prevention of cancer in patients that are not suffering from cancer, as discussed hereinabove. Thus, a person of skill in the art would not have turned to Thun et al. for combining a NSAID with curcumin for treating cancer.

However, there is nothing in either Thun et al., and/or in Kawamori et al., which suggests that a reduced concentration of NSAID can be used in inhibiting cancer, especially by combining curcumin with the NSAID to treat cancer. Appllicants additionally submit that nothing in Thun et al. and/or in Kawamori et al. points to a synergetic effect in combining NSAID and curcumin, as evident from the present specification.

As set forth at page 26, lines 17-21 of the present specification, it has been demonstrated that "in the presence of low concentrations of curcumin (10-15 μM), a physiological concentration of celecoxib (5 uM) is sufficient to inhibit cell growth by inhibiting proliferation and inducing apoptosis, by COX-2 and non-COX-2 pathways. This effect is similar to that achieved with a 10-fold higher concentration of celecoxib (50 uM) when administered alone. Similar results were obtained for curcumin and sulindac (Fig. 3), for curcumin and sulindac sulfide (Fig. 4) and for curcumin and nimesulide (Fig. 5).

Kawamori et al. states that "the effects of curcumin demonstrated here resemble those of NSAIDs and thus seem to act strongly via inhibition of arachidonate metabolism and through reducing cell proliferation and inducing apoptosis." *See* Kawamori et al. at page 600, 2nd column, bottom of middle paragraph. Kawamori et al., further states that "this study further extends earlier observations that synthetic NSAIDs, such as piroxicam and sulindac, given during the promotion/progression period protect against tumorigenesis...." *Id.* at page 600, 2nd column, lines 9-12. Thun et al. states that "other drugs that have also been used in combination with either sulindac, aspirin or piroxicam include...the spice curcumin...." *See* Thun et al. at page 255, 2nd column, first full paragraph.

However, neither Thun et al. nor Kawamori et al. teach or even suggest any level of complementary contribution whatsoever between a NSAID and curcumin to allow a lower concentration of NSAID to maintain the same therapeutic effect as compared to administering the NSAID alone. Thus, the presently claimed subject matter is novel and non-obvious.

Accordingly, Applicants submit that none of the cited references, whether taken alone or in combination, render the presently claimed subject matter obvious, within the meaning of 35 USC § 103(a) Thus, reconsideration and withdrawal of this rejection is respectfully requested.

VI. At page 18 of the Official Action, claims 1, 3-5, 9-15, 20, 21, 23-25 and 32 have been rejected under 35 USC § 103(a) as being unpatentable over Metaproteomics LLC (WO 03/007975 A 1) and Samaha et al. (Cancer Research, 1997).

The Examiner asserts that claims 1, 3-5, 9-15, 20, 21, 23-25 and 32 are obvious for the reasons set for the in the Official Action.

In view of the following, the rejection of claims 1, 3-5, 9-15, 21, 23-25 and 32 is respectfully traversed. In addition, Applicants note that the cancellation of claim 20 has rendered the rejection of the same moot.

A brief outline of the relevant authority on obviousness is discussed above in § V, and is hereby incorporated herein by reference to the same.

Applicants submit that a *prima facie* case of obviousness has not been established because whether taken alone or together, neither Metaproteomics LLC nor Samaha et al. teach or suggest the use of curcumin and an NSAID or curcumin and a NSAID in an amount lower than those acceptable in mono-therapy (treatment with an NSAID drug alone), while maintaining the same therapeutic effect as compared to administering the NSAID alone, as claimed.

Claims 1, 3-5, 9-15, 21, 23-25 and 32 are each discussed above in § V, by way of the discussion of independent claims 1, 12 and 32. As discussed above, claims 1, 3-5, 9-

15, 21, 23-25 and 32 are each, in part, directed to using curcumin, analogues and derivatives thereof, to reduce the NSAID concentration needed for treatment, while maintaining the same therapeutic effect as compared to administering the NSAID alone.

In contrast, Metaproteomics LLC is directed to synergistic compositions comprising curcuminoids and NSAIDs such as ditropen lactone species and trierpene species.

However, unlike the claimed subject matter, Metaproteomics LLC does not teach or suggest curcumin present in an amount that is sufficient to reduce the NSAID concentration required while maintaining the same therapeutic effect as compared to administering the NSAID alone, as recited in pending claim 1 and amended claim 12. In this regard, the Examiner's attention is politely directed to page 3 of Metaproteomics LLC, which states that "... it would be useful to identify a composition that would specifically enhance the anti-inflammatory effect of curcuminoids so that they could be used at sufficiently low doses or at a current clinical doses with no adverse side effects." *See* Metaproteomics LLC at page 3, lines 26-29.

As suggested by the cited text, Applicants submit that Metaproteomics LLC is directed to obtaining combinations of curcuminoids and other compounds or botanical extracts that increase COX-2 specificity of curcuminoids to provide an improved anti-inflammatory composition. Specifically, from the above cited paragraph, it is clear that the aim of Metaproteomics LLC is to identify curcuminoids that could be used at a low concentration, e.g., to avoid the gastro-intestinal upset and stomach irritation caused by high doses of curcuminoids] rather than reduce the concentration of NSAIDS "required to achieve the same therapeutic effect...." *Id.*

In addition, Applicants submit that Metaproteomics LLC does not teach or suggest a composition comprising curcuminoids and NSAIDS, let alone a combination in which "the curcumin being in an amount sufficient to reduce the NSAID concentration needed while maintaining the same therapeutic effect as compared to administering the NSAID alone," as claimed. In fact, Metaproteomics LLC does not disclose a composition and/or a formulation comprising any amount of curcuminoids and NSAIDs but only discloses a "composition comprising an effective amount of a curcuminoid species and an effective amount of a diterpene lactone species, the triterpene species or derivative thereof...." See Meta proteomics LLC at claim 1. Therefore, Metaproteomics LLC does not teach or suggest every element of the claimed subject matter.

Samaha et al. do not remedy the deficiencies of Metaproteomics LLC. Samaha et al. describe the effect of sulindac, curcumin, PEMC (phenylethyl-3-methylcaffeate) PHITC (6-phenylhexyl isothiocyanate) on apoptosis in a rat colon- caner model. Fig. 1 of Samaha et al. (page 1302, right column) shows that sulindac, curcumin PEMC, PHITC are tested separately as compared to a control (depicted in left histogram). Samaha et al. do not teach or suggest the combined administration of curcumin and a NSAID (e.g. sulindac). In addition, a person of skill in the art, reading Samaha et al., would not have expected a combination of curcumin and a NSAID to enable the reduction of a NSAID concentration while maintaining the same therapeutic effect as compared to administering the NSAID alone because Samaha et al. do not disclose a combination of curcumin and a NSAID in the first place. Therefore, whether taken alone or combination, neither Metaproteomics

LLC nor Samaha et al. teach or suggest the use of curcumin and an NSAID or curcumin and a NSAID in an amount lower than those acceptable in mono-therapy (treatment with an NSAID drug alone), while maintaining the same therapeutic effect as compared to administering the NSAID alone, as claimed.

Accordingly, Applicants submit that none of the cited references, whether taken alone or in combination, render the presently claimed subject matter obvious, within the meaning of 35 USC § 103(a) Thus, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

/Ari G. Zytcer/
Susanne M. Hopkins
Registration No. 33,247
Ari G. Zytcer
Registration No. 57,474
Customer No. 20529

Date: February 7, 2011
THE NATH LAW GROUP
112 S. West Street
Alexandria, VA 22314
Tel: (703) 548-6284
Fax: (703) 683-8396